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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,248	09/17/2001	Leo Martis	DI-4641 CONT	8992

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EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/955,248	<b>Applicant(s)</b> MARTIS ET AL.	
	<b>Examiner</b> Rosalynd Keys	<b>Art Unit</b> 1621	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

**DETAILED ACTION**

***Status of Claims***

1. Claims 1-16 are pending.

Claims 1-16 are rejected.

***Response to Board Decision***

2. In view of the *Reversal* from the Board of Patent Appeals and Interferences on July 28, 2004 the following rejections are withdrawn:

1) Rejection of claims 1, 2, 4 and 5 under 35 U.S.C. 102(b) as being anticipated by Veech (US 4,663,166) in view of Zander (US Patent No. 5,296,242).

2) Rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Veech et al. (US 4,663,166) in view of Zander (U.S. Patent No. 5,296,242).

3) Rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Veech (US 6,020,007) in view of Zander (US 5,296,242).

3. In view of the *Remand* from the Board of Patent Appeals and Interferences on July 28, 2004, PROSECUTION IS HEREBY REOPENED. The new grounds of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

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If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### **Examiner's Comments**

#### Schambye

The Examiner has reviewed the data for solution 91c, per the Boards recommendation. However, since the data presented for solution 91c is not sufficient for the Examiner to determine the carbon dioxide partial pressure, the burden shifts to the Applicants to prove that the peritoneal dialysis solution disclosed in Schambye et al. does not necessarily or inherently possess the claimed carbon dioxide partial pressure In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). If Applicants cannot readily determine the carbon dioxide partial pressure of solution 91c of Schambye, either from the data presented in Schambye or by determination of the pKa through experimentation, the applicants should specifically state for the record why it is impossible to determine the carbon dioxide partial pressure of solution 91c of Schambye. The Examiner is not able to make a determination because according to Zander the CO<sub>2</sub> partial pressure is determined from the reaction between the bicarbonate and metabolizable organic acid. This reaction would need to be performed in a laboratory setting, which the Examiner has no access to.

#### Veech

The Examiner has reviewed the data for the preferred peritoneal dialysis solution in Table VIII of Veech, per the Boards recommendation. However, since the data

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presented for the preferred solution is not sufficient for the Examiner to determine the carbon dioxide partial pressure, the burden shifts to the Applicants to prove that the peritoneal dialysis solution disclosed in Veech does not necessarily or inherently possess the claimed carbon dioxide partial pressure In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). If Applicants cannot readily determine the carbon dioxide partial pressure of the preferred solution of Veech, either from the data presented in Veech or by determination of the pKa through experimentation, the applicants should specifically state for the record why it is impossible to determine the carbon dioxide partial pressure of the preferred solution of Veech. The Examiner is not able to make a determination of the CO<sub>2</sub> partial pressure because according to Zander the CO<sub>2</sub> partial pressure is determined from the reaction between the bicarbonate and metabolizable organic acid. This reaction would need to be performed in a laboratory setting, which the Examiner has no access to.

#### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242).

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Schambye et al. disclose continuous ambulatory peritoneal dialysis (CAPD) solutions having bicarbonate concentrations ranging from 10-27 mM, lactate concentrations ranging from 20.0-6.7 mM (see abstract on page S116). The most advantageous CAPD solution has a bicarbonate concentration of approximately 20 mM, a lactate concentration of 12.5 mM, and a pH of approximately 7.2 (see page S116, abstract and page S118). Since, Schambye et al. disclose a CAPD solution which has the claimed bicarbonate and weak acid concentrations then the CAPD solution of Schambye et al. inherently exhibit the claimed CO<sub>2</sub> partial pressure (see In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986), since it is the bicarbonate and weak acid that determine the CO<sub>2</sub> partial pressure (see Zander at column 3, lines 11-16, wherein it is taught that the reaction between the bicarbonate and metabolizable organic acid produces the CO<sub>2</sub> partial pressure).

The burden shifts to the Applicants to prove that the peritoneal dialysis solution disclosed in Schambye et al. does not necessarily or inherently possess the claimed carbon dioxide partial pressure. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

6. Claims 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (US 4,663,166) in view of Zander (US Patent No. 5,296,242).

Veech discloses preferred peritoneal dialysis solutions comprising osmotically active substances such as glucose (dextrose, 83-237 mmole/L, i.e., 1.49-4.27 g/dL), sodium (130 to 145 mmole/L), chloride (93 to 102 mmole/L), calcium (1 to 1.5 mmole/L), magnesium (0.3 to 1 mmole/L), bicarbonate (25 to 30 mmole/L), lactate/plus pyruvate

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(2 to 12) and carbon dioxide ( 0 to 2 mmole/L), see column 41, table VIII and column 37, line 41.

Veech discloses a peritoneal dialysis solution, which has the claimed bicarbonate and weak acid concentrations. Therefore, the peritoneal dialysis solution of Veech inherently exhibits the claimed CO<sub>2</sub> partial pressure (see In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986), since it is the bicarbonate and weak acid that determine the CO<sub>2</sub> partial pressure (see Zander at column 3, lines 11-16, wherein it is taught that the reaction between the bicarbonate and metabolizable organic acid produces the CO<sub>2</sub> partial pressure).

The burden shifts to the Applicants to prove that the peritoneal dialysis solution disclosed in Veech does not necessarily or inherently possess the claimed carbon dioxide partial pressure. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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9. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242).

Schambye et al. disclose a peritoneal dialysis solution as described above. Schambye et al. differ from the instant invention in that Schambye et al. do not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO<sub>2</sub> partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value  $7.40 \pm 0.05$ , for the bicarbonate concentration 24 mmole/l and for the CO<sub>2</sub> partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values ( $7.40 \pm 0.05$ ), bicarbonate concentrations (24 mmole/L) and CO<sub>2</sub> partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Schambye et al. in such a way as to obtain a pCO<sub>2</sub> that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO<sub>2</sub>

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partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

10. Claims 6-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech et al. (US 4,663,166) in view of Zander (U.S. Patent No. 5,296,242).

Veech discloses peritoneal dialysis solutions as described above. The peritoneal solutions disclosed in Veech tend to maintain a normal equivalent ratio of sodium to chloride, tend to maintain normal plasma and cellular pH and tend to maintain normal cofactor ratios (see column 41, lines 9-14). Thus, upon its use the peritoneal dialysis solution of Veech would inherently correct metabolic acidosis in a dialysis patient suffering from or likely to suffer from metabolic acidosis.

Veech differs from the instant invention in that Veech does not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO<sub>2</sub> partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value  $7.40 \pm 0.05$ , for the bicarbonate concentration 24 mmole/l and for the CO<sub>2</sub> partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values ( $7.40 \pm 0.05$ ), bicarbonate concentrations (24 mmole/L) and CO<sub>2</sub>

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partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Veech in such a way as to obtain a  $p\text{CO}_2$  that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using  $\text{CO}_2$  partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

Veech further differs from claim 15, in that Veech teaches utilizing lactate as the weak acid, whereas claim 15 requires that the solution does not contain lactate.

Zander teaches that in peritoneal dialysis solutions the metabolizable acids can be selected from pyruvic, lactic, oxalic, fumaric, acetic, malic, maleic, malonic and succinic acids. Thus, these acids are taught to be interchangeable.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the lactic acid of Veech with any of the metabolizable acids taught by Zander, since Zander implicitly teaches that these acids are equivalent for their use in the peritoneal dialysis art and the selection of any of these known equivalents as the weak acid in Veech would be within the level of ordinary skill in the art.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 571-272-

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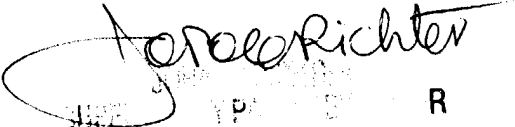
0639. The examiner can normally be reached on M, R and F 3:00-8:00 pm and T-W 5:30-10:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Rosalyn Keys  
Primary Examiner  
Art Unit 1621

September 30, 2004

  
Johann Richter  
GROUP 1200 R